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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,664

01/26/2004

Leonard S. Girsh

GIR-105CXC1

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO Box 142950
GAINESVILLE, FL 32614

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

03/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,664	GIRSH, LEONARD S.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-12 are pending.

Applicants' amendment filed December 24, 2008 is acknowledged. Applicants' response has been fully considered. Claims 1, 7 and 8 have been amended, and new claims 9-12 have been added. Therefore, claims 1-12 are examined.

Withdrawn Claim Rejections - 35 USC § 103

2. The previous rejection of claims 1-4 and 6 under 35 U.S.C. 103(a) as being unpatentable over Kose (US 2004/0156886, filed June 12, 2002), is withdrawn in view of applicants' amendment to the claims, and applicant's response at pages 5-6 in the amendment filed December 24, 2008.

Withdrawn Claim Rejections - Obviousness Type Double Patenting

3. The previous rejection of claims 1-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 11-27 of co-pending application 10/868,697, is withdrawn in view of applicants' submission of a terminal disclaimer, and applicant's response at page 6 in the amendment filed December 24, 2008.

New Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent 6,974,796. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 in the instant application disclose an anabolic composition comprising (a) cartilage, chondroitin sulfate, hyaluronic acid or collagen in an amount to act as anti-neo-inflammatory and anti-neo-angiogenetic agent; (b) about 1 to 3 grams of at least one polar surface active lipid such as lecithin, phosphatidylserine, and others; (c) a plurality of L-amino acids and glycine; (d) taurine and/or L-carnitine; (e) a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, or combinations thereof; and (f) vitamin B12, vitamin E, selenium, zinc or combination thereof; and the composition may further comprise omega three fatty acid or a compound generally accepted as safe (GRAS). This is obvious variation in view of claims 1-19 of the patent which disclose an anabolic composition comprising (a) at least one extracellular matrix compound of glycosaminoglycan, a collagen, cartilage, chondroitin sulfate, a glycoprotein and a proteoglycan as anti-neo-inflammatory and anti-neo-angiogenetic agent; (b) at least one polar surface active lipid of a phospholipid, a glycolipid and a lipolipid; and (c) a plurality of L-amino acids at a molar ratio of characteristic of human breast milk protein (e.g. Neocate), and the composition may further comprise L-carnitine or an omega three fatty acid such as linolenic acid. Both sets of claims are directed to an anabolic composition comprising at least one extracellular matrix compound; at least one polar

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surface active lipid; and a plurality of L-amino acids such as Neocate; and the composition may further comprise L-carnitine or an omega three fatty acid such as linolenic acid. Thus, claims 1-12 of the present application and claims 1-19 in the patent are obvious variations of an anabolic composition comprising at least one extracellular matrix compound; at least one polar surface active lipid; a plurality of L-amino acids such as Neocate; and the composition may further comprise L-carnitine or an omega three fatty acid such as linolenic acid.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
March 4, 2009